IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

(Attorney Docket No. 07-2123)

In re Application of:	)	
	)	
Larsson	)	
	)	Group Art Unit 3761
Serial No. 10/579,982	)	
	)	Examiner: Treyger, I.
Filed: May 19, 2006	)	
	)	Conf. No. 3593
For: Drainage Apparatus & Method	)	

OPENING APPEAL BRIEF

Michael H. Baniak
Kirsten L. Thomson
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

Table of Contents

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

I. Real Party in Interest

The real party in interest is Medela Holding AG, to which this invention is assigned.

II. Related Appeals and Interferences

Appellant is not aware of any related appeals or interferences.

III. Status of Claims

Pending claims 1-11 and 14-16, of which claims 1, 11, and 16 are independent and the remainder are dependent. Claims 12 and 13 are cancelled.

Claims 1-11 and 14-16 are under appeal.

A clean set of the pending claims is attached in the Claims Appendix.

IV. Status of Amendments

Claims 11 and 16 were amended to correct a typographical error after final rejection. The subsequent advisory action dated February 12, 2010 did not address the amendments. Therefore Appellant's understanding is that the foregoing corrective amendments were not entered.

V. Summary of Claimed Subject Matter

As noted above, there are two independent claims involved in the appeal: claims 1, 11 and 16. Claim 1 is for an apparatus, and claims 2-10 are dependent therefrom, whereas claims 11 and 16 are directed to a method, with claims 14-15 dependent from claim 11.

Claim 1 is drawn to an apparatus for removing body fluids from a body cavity by suction. The apparatus comprises: (a) a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen (*See, e.g.*, Specification, p. 4, lines 3-9; Fig. 1, #3-5); (b) a container for connection in

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity (*See, e.g.*, Specification, p. 4, lines 1-3, 29-30; Fig. 1, #2-3); (c) a source of suction for effecting negative pressure in the drainage lumen (*See, e.g.*, Specification, p. 3, lines 30-31; p. 4, lines 18-20; Fig. 1, #1, 3); (d) a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity (*See, e.g.*, Specification, p. 4, lines 11-21; Fig. 1, #5, 7); and (e) wherein, for removing clots or plugs in the drainage lumen, the apparatus further comprises a first pressure sensor for measuring the pressure in the auxiliary lumen and a controller to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure (*See, e.g.*, Specification, p. 4, lines 14-16; p. 4, line 27 to p. 5, line 15; Figs. 1-3, #3, 5, 6, 8).

Under claim 11, the method relates to operating an apparatus for removing body fluids from a body cavity by suction. The apparatus comprises: (a) a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen (*See, e.g.*, Specification, p. 4, lines 3-9; Fig. 1, #3-5); (b) a container for connection in fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity (*See, e.g.*, Specification, p. 4, lines 1-3, 29-30; Fig. 1, #2-3); (c) a source of suction for effecting negative pressure in the drainage lumen and a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity (*See, e.g.*, Specification, p. 3, lines 30-31; p. 4, lines 18-20; Fig. 1, #1, 3). The method comprises the steps of: (a) measuring the pressure in the auxiliary lumen (*See, e.g.*, Specification, p. 4, lines 14-16; p. 4, line 27 to p. 5, line 15; Figs. 1-3, #5, 6); (b) opening the auxiliary lumen (*See, e.g.*,

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

Specification, p. 5, lines 2-4, 21-25; Figs. 1-3, #5, 7); and (c) increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure, wherein the pressure difference is increased by increasing the power of the source of suction (*See, e.g.*, Specification, p. 5, lines 1-31; Figs. 1-3, #1, 3, 5, 7).

According to claim 16, the method involves removing body fluids from a body cavity by suction. The method comprises: (a) providing a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen (*See, e.g.*, Specification, p. 4, lines 3-9; Fig. 1, #3-5); (b) providing a container for connection in fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity (*See, e.g.*, Specification, p. 4, lines 1-3, 29-30; Fig. 1, #2-3); (c) providing a source of suction for effecting negative pressure in the drainage lumen (*See, e.g.*, Specification, p. 3, lines 30-31; p. 4, lines 18-20; Fig. 1, #1, 3); (d) providing a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity (*See, e.g.*, Specification, p. 4, lines 11-21; Fig. 1, #5, 7); (e) measuring the pressure in the auxiliary lumen (*See, e.g.*, Specification, p. 4, lines 14-16; p. 4, line 27 to p. 5, line 15; Figs. 1-3, #5, 6); (f) opening the auxiliary lumen (*See, e.g.*, Specification, p. 5, lines 2-4, 21-25; Figs. 1-3, #5, 7); and increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure, wherein the pressure difference is increased by increasing the power of the source of suction (*See, e.g.*, Specification, p. 5, lines 1-31; Figs. 1-3, #1, 3, 5, 7).

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

VI. Grounds of Rejection to Be Reviewed on Appeal

Claims 1-11 and 14-16 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 4, 536,180 (Johnson) in view of U.S. Patent No. 7,025,718 (Williams).

VII. Argument

a. Rejection under 35 U.S.C. § 103(a) over Johnson in view of Williams

The examiner's rejection of the Claims is improper because the *prima facie* case for obviousness has not been established; indeed, far from it. According to the M.P.E.P. §§ 2142 and 2143, the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) with rational underpinning to support the conclusion of obviousness. In particular, § 2142 explains: "The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. [398, 418], 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that 'rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *In re Kahn*, 441 F.3d 977, 988 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). *See also KSR*, 550 U.S. at [418], 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)."

The Examiner's reliance on Johnson and Williams as allegedly teaching the subject matter of independent claims 1, 11 and 16 is factually flawed. Therefore, the Examiner's rejection of claims 1 and 16 lacks the rational underpinnings necessary to establish *prima facie* obviousness under M.P.E.P. § 2142.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

i. Clear Error in Rejection of Claims 1-10

As noted above, independent claim 1 stands rejected as being allegedly obvious over Johnson in view of Williams. Appellant submits that this rejection was improper and should be withdrawn, because Johnson is clearly deficient, as indicated by the Examiner; Williams does not make up for the deficiency of Johnson. At a minimum, for instance, the combination does not disclose or render obvious the claim 1 feature of *a **first pressure sensor** for measuring the pressure in the auxiliary lumen and **a controller** to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure*.

In order to clear hard or fibrous material from the passage of a lumen, Johnson has a surgeon manually open a valve apparatus with his thumb. Johnson, col. 4, lines 19-20, 38-53. Air then bleeds into a venting passage 18 and around the end of divider member 14 at a point beyond the opening in the suction passage 16. *Id.* The application of air at the end portion "allows the vacuum applied at the other end to pull the plug material on through without having to continue to pull on the bodily material adjacent to the side opening 15." *Id.* Johnson does not have or suggest a controller to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open.

Further, the Examiner admitted that Johnson does not disclose the claim 1 feature of *a first pressure sensor for measuring the pressure in the auxiliary lumen. See Office Action Mailed 09-16-2009*, p. 3 ("Johnson does expressly disclose the apparatus comprising a pressure sensor for measuring the pressure in the lumen."). In an effort to make up for this admitted deficiency, the Examiner turned to Williams for this disclosure.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

Williams shows "introducing a balloon into the thoracic aorta of a patient and causing the balloon to inflate and deflate in anti-phase with the contraction of the patient's heart." Williams, col. 5, lines 3-6. According to Williams, "[p]ressure sensor 55, continuously measures the pressure of shuttle gas in the [intra-aortic balloon] shuttle gas pneumatic circuit and communicates with the control logic module 16." *Id.* at col. 5, lines 29-32. Additionally, Williams says that "[u]pon command from control logic module 16, pneumatic drive module 14 inflates or deflates the balloon membrane 26" *via a single inflate/deflate control line 20. Id.* at col. 5, lines 27-29; col. 6, lines 23-25. Williams has a closed system with a single control line for inflating and deflating a balloon in rhythm with a heart.

Williams does not provide the claimed feature at hand, specifically because there is no teaching of *a first pressure sensor for measuring the pressure in the auxiliary lumen*. Notably, Williams does not teach an apparatus designed to remove fluid or tissue from the body. It does not remove anything. Williams' disclosed device is drawn to a very different purpose in a very different environment than that recited in Appellant's claims, which are for removing bodily fluids from a body cavity by suction. There is no suggestion or reason to look to Williams to supply the deficiencies of Johnson, and the Examiner has failed to provide any such reason or link.

The Advisory Action mailed December 15, 2009 attempts to avoid the fact that Williams is non-analogous art, but acknowledges that a reference must "be reasonably pertinent to the particular problem with which the [Appellant] was concerned." The Action then alleges that "Williams solves the same problem as claimed by the [Appellant], i.e. *maintaining* pressure in the lumen." This assertion is, respectfully, wrong. For example, the device of Appellant's claim 1 requires "a controller to *increase the pressure difference* between a pressure in the drainage

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

lumen and a pressure in the atmosphere." In addition, Appellant's claim 1 recites "[a]n apparatus for *removing body fluids* from a body cavity by suction" and "for *removing clots or plugs* in the drainage lumen." But William's has a closed system with a single control line for inflating and deflating a balloon in rhythm with a heart. Williams therefore does not even supply the missing pieces of Johnson, so as to provide all of the claim limitations.

Appellant submits that the Examiner failed to provide any articulation of the reason why Appellant's claimed invention would have been obvious, in view of these disparate (indeed non-analogous in one instance) references, and thus that the Action has not established *prima facie* obviousness of claim 1. Further, Appellant submits that claims 2-10 are allowable as well for at least the reason that they depend from allowable claim 1.

Because the invention of claim 1 does not reasonably or logically follow from the limited teachings of Johnson in view of Williams, *prima facie* obviousness of claim 1 over Johnson in view of Williams does not exist. Therefore, the Examiner clearly erred in rejecting claim 1, and claims 1-10 should be allowed.

ii. Clear Error in Rejection of Claims 11 and 14-16

Claims 11 and 16 are independent and stands rejected as being allegedly obvious, again, over Johnson in view of Williams.

Here again, Appellant submits that the rejection is improper and should be withdrawn, because the combination of Johnson and Williams does not teach all the elements of claims 11 or 16. At a minimum, for instance, the combination of Johnson and Williams does not teach the limitation, for example, of *increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when the pressure measured in the auxiliary lumen*

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

corresponds at least to atmospheric pressure, wherein the pressure difference is increased by increasing the power of the source of suction.

Per the discussion above, Johnson manually opens a valve to allow air to enter a venting passage when material plugs a suction passage. Noticeably absent is any teaching that *the pressure difference is increased by increasing the power of the source of suction*, as recited in claim 16. And Johnson's teaching that its vacuum source is "controllable" is irrelevant, because Johnson simply does not teach *increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when* ***the pressure measured*** *in the auxiliary lumen corresponds at least to atmospheric pressure.* The Office Action mailed September 16, 2009 reinforces this point by admitting that Johnson does not disclose a pressure sensor. *Office Action Mailed 09-16-2009*, p. 3.

Williams has a closed system with a single inflate/deflate control line, not an auxiliary lumen *and* a drainage lumen. Williams does not operate to remove body fluids from a cavity. So there is no *pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere* taught in Williams that could be increased as claimed. There is no suction to remove body fluids, and therefore Williams does not teach *increasing the power of the source of suction.* Here once more, Williams and Johnson do not "add up" to all of the claimed elements and limitations. *Ab initio*, missing limitations from the claims even when summed together, they cannot equal a basis for a §103 rejection. As with the arguments made above with respect to claims 1-10, the combination of Johnson and Williams is improper as to claims 11 and 16 (and dependent claims 14-15).

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

b. Conclusion

In view of the foregoing, Applicant submits that all of the pending claims are in condition for allowance. Therefore, Applicant respectfully requests favorable reconsideration and allowance of all the claims.

Respectfully submitted,

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP

Date: April 16, 2010

By: /Kirsten L. Thomson/
Kirsten L. Thomson
Reg. No. 62,861

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

CLAIMS APPENDIX

1. (previously presented) An apparatus for removing body fluids from a body cavity by suction, comprising:

a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen;

a container for connection in fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity;

a source of suction for effecting negative pressure in the drainage lumen; a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity;

wherein, for removing clots or plugs in the drainage lumen, the apparatus further comprises a first pressure sensor for measuring the pressure in the auxiliary lumen and a controller to increase the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere when the auxiliary lumen is open only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure.

2. (previously presented) The apparatus of claim 1 wherein the source of suction is a suction pump and the controller controls the suction power of the suction pump.

3. (previously presented) The apparatus of claim 1, wherein the first pressure sensor is in communication with the controller.

4. (previously presented) The apparatus of claim 1 wherein the controller is in communication with the valve for opening the auxiliary lumen.

5. (previously presented) The apparatus of claim 1 wherein the pressure difference can be increased to achieve a negative pressure level in the drainage lumen being at least half of the

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

negative pressure level during drainage.

6. (previously presented) The apparatus of claims 1 further comprising a means for measuring the pressure in at least one of the group of the container and the drainage lumen.

7. (previously presented) The apparatus of claim 6 wherein this means is a second pressure sensor.

8. (previously presented) The apparatus of claim 7, wherein the controller is in communication with the second pressure sensor.

9. (previously presented) The apparatus of claims 1 wherein the controller is increasing the pressure continuously.

10. (previously presented) The apparatus of claims 1, wherein the controller is increasing the pressure abruptly.

11. (previously presented) A method for operating an apparatus for removing body fluids from a body cavity by suction, the apparatus comprising:

a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen;

a container for connection in fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity;

a source of suction for effecting negative pressure in the drainage lumen and a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity;

the method comprising the steps of

measuring the pressure in the auxiliary lumen,

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

opening the auxiliary lumen; and

increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure, wherein the pressure difference is increased by increasing the power of the source of suction.

12. (canceled)

13. (canceled)

14. (previously presented) The method of claim 11 wherein the auxiliary lumen is opened by opening a first valve.

15. (previously presented) The method of claim 14 wherein the source of suction is controlled by a controller and wherein the controller is in communication with at least one of the group of the valve and a first pressure sensor measuring the pressure in the auxiliary lumen.

16. (previously presented) A method for removing body fluids from a body cavity by suction, the method comprising the steps of:

providing a catheter having a drainage lumen and an auxiliary lumen adapted for placement adjacent a wound in the body cavity to be drained of body fluid, the drainage lumen having a proximal end being in fluid communication with a proximal end of the auxiliary lumen;

providing a container for connection in fluid communication with the drainage lumen and for receiving body drainage fluid from the body cavity;

providing a source of suction for effecting negative pressure in the drainage lumen and

providing a valve for opening the auxiliary lumen in order to supply air or gas to the body cavity

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

the method further comprising the steps of

measuring the pressure in the auxiliary lumen,

opening the auxiliary lumen; and

increasing the pressure difference between a pressure in the drainage lumen and a pressure in the atmosphere only when the pressure measured in the auxiliary lumen corresponds at least to atmospheric pressure, wherein the pressure difference is increased by increasing the power of the source of suction.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

EVIDENCE APPENDIX

This appendix is empty.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001

RELATED PROCEEDINGS APPENDIX

This appendix is empty.

McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
TELEPHONE (312) 913-0001